



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,431	03/05/2001	Victoria Beck	00231-088002 / USSN 09/22	2545

26161 7590 08/26/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

CHISM, BILLY D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,431

Applicant(s)

BECK ET AL.

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. -See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-36 is/are allowed.
- 6) ☒ Claim(s) 1-20 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1654

DETAILED ACTION

This Office Action is in response to Paper No. 9, filed 25 April 2003, wherein claims 21-29 were canceled, and claims 1-20 and 30-39 are pending.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments will be addressed to the extent that they pertain to the present grounds of rejection.

Objections

Objections to the disclosure were obviated by Applicants' response.

Objections to the claims for grammar were obviated by Applicants' response.

Claim Rejections - 35 USC § 112

1. (Maintained) Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for autism, does not reasonably provide enablement for the spectrum of disorders possible under the heading of pervasive development disorder (PDD). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For the reasons stated in the previous office action, the specification is enabled for autism only and not the full range of PDDs of which autism may be found. Thus, the amendments to claims 1 and 16 do not obviate the original objection for scope of enablement.

Art Unit: 1654

2. (Maintained) Claim 11 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transdermal administration, does not reasonably provide enablement for the transdermal administration of secretin by methods of acoustic waves. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

For the reasons stated in the previous office action, the specification is enabled for transdermal administration only. Applicants argue that the specification at page 13, line 28 to page 14, line 5 affords adequate detail for enablement for the use of acoustic waves for transdermal administration of secretin. However, Applicants' recitation of the specification, while meeting the guidelines of written description, does not obviate the enablement rejection, wherein it is not known if transdermal administration of secretin by methods of acoustic waves would be probable for any patient at any time given any concentration or any dosage or formulation. Therefore, the rejection is maintained.

3. (Maintained) Claims 19-20 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants argue an enablement issue for the claims but this is an indefinite claim to a method without comprising method steps. Therefore, the claims remain rejected.

4. (Necessitated by Amendment) Claim 4 is rejected for the indefinite recitation of "re" wherein the claim should read "per".

Art Unit: 1654

5. (Necessitated by Amendment) Claims 37-39 are rejected for depending from rejected claim 11.
6. (Withdrawn) Rejection of claim 30 as improperly depending upon itself is withdrawn, as the inclusion of claim 30 was an error as pointed out by Applicants.
7. (Withdrawn) Rejection of claims 4, 8, 32 and 36 for "clinical unit (CU)" is withdrawn due to Applicants arguments.
8. (Withdrawn) Rejection of claims 6, 10-11 and 34 for "portion of the skin" is withdrawn due to Applicants arguments.

Nonstatutory Double Patenting

9. (Withdrawn) Rejection of claims 1-4, 7, 30-32 and 35, for the judicially created doctrine of obviousness-type double patenting over claims 1, 3 and 9 of US 6,020,310, is withdrawn wherein Applicants filed the required Terminal Disclaimer.
10. (Withdrawn) Rejection of claims 1-2, 5-10, 17, 30 and 35-36, for the judicially created doctrine of obviousness-type double patenting over claims 1-2, 5-10, 17, 30 and 33-36 of US 6,197,746, is withdrawn wherein Applicants filed the required Terminal Disclaimer.

Conclusions

Claims 30-36 are allowable.

11. Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

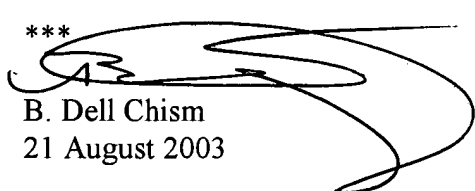
Art Unit: 1654

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


B. Dell Chism
21 August 2003


CHRISTOPHER R. TATE
PRIMARY EXAMINER